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Registration Decision

Fenamidone

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Registration Decision for Fenamidone

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Fenamidone Technical Fungicide and Reason 500 SC Fungicide containing the technical grade active ingredient fenamidone applied with ground or aerial equipment to control early and late blight on potatoes.

Current scientific data from the applicant were evaluated to determine if, under the proposed conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document¹: Proposed Registration Decision - *Fenamidone* (PRD2007-07). This Registration Decision² describes this stage of the PMRA's regulatory process for Fenamidone and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2007-07. This decision is consistent with the proposed registration decision stated in PRD2007-07.

For more details on the information presented in this Registration Decision, please refer to the related Proposed Registration Decision PRD2007-07, *Fenamidone*, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration.³ The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act* is "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and c) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What Is Fenamidone?

Fenamidone is the active ingredient in the end-use product Reason 500 SC Fungicide. Reason 500 SC Fungicide, containing 500 g/L of fenamidone, is a flowable concentrate fungicide to control early and late blight on potatoes. Reason 500 SC Fungicide can be applied with ground or aerial application equipment when it is tank-mixed with Dithane DG or Bravo 500.

Health Considerations

Can Approved Uses of Fenamidone Affect Human Health?

Fenamidone is unlikely to affect your health when used according to the proposed label directions.

A toxicology assessment of fenamidone and Reason 500 SC Fungicide is presented in Regulatory Note REG2003-11, *Fenamidone Technical Fungicide, Reason 500 SC Fungicide*.

Residues in Water and Food

Dietary risks from food and water are not of concern.

A dietary risk assessment of fenamidone and Reason 500 SC Fungicide is presented in Regulatory Note REG2003-11.

Aggregate dietary intake estimates (food plus water) revealed that the general population and children 1 to 2 years old, the subpopulation which would ingest the most fenamidone relative to body weight, are expected to be exposed to less than 5% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from fenamidone is not of concern for all population subgroups. There is no lifetime cancer risk from the use of fenamidone.

Animal studies revealed no acute health effects. Consequently, a single dose of fenamidone is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Each MRL value determines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Pesticide MRLs are established for the *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Information submitted was sufficient to show that N-phenyl anilines do not form from the metabolism of fenamidone in plants. No new MRLs are being recommended at this time.

Occupational Risks From Handling Fenamidone

Occupational risks are not of concern when fenamidone is used according to the proposed label directions, which include protective measures.

An occupational risk assessment of fenamidone and Reason 500 SC Fungicide is presented in Regulatory Note REG2003-11.

Direct skin contact can occur with fenamidone when farmers and pesticide applicators are mixing, loading or applying Reason 500 SC Fungicide, and when field workers re-enter freshly treated fields. Therefore, the label specifies that anyone mixing or loading Reason 500 SC Fungicide must wear a long-sleeved shirt, pants, boots, protective eyewear and chemical-resistant gloves. Taking into consideration these label requirements and that occupational exposure is expected to be of short to intermediate duration, risk to farmers, applicators or workers is not a concern.

For bystanders, the exposure is expected to be much less than that of field workers, which is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Fenamidone Is Introduced Into the Environment?

Fenamidone is introduced into the environment when used as a fungicide on potatoes. Fenamidone is non-persistent in soil, while its major transformation products are expected to be moderately persistent to persistent in soil. Although the use pattern of this product does not include direct application to water, the possibility that aquatic systems will be exposed to fenamidone, directly or indirectly, cannot be ruled out. In an aquatic environment, fenamidone readily partitions from water to sediments, where it persists.

Laboratory studies of mobility indicated that fenamidone and its major transformation products have moderate to high mobility in soils and sediment; however, no leaching of these compounds was observed below the 15-centimetre depth under field conditions. Based on fenamidone's low volatility, its residues are not expected in the air.

The *n*-octanol-water partition coefficient of fenamidone and its major transformation products indicate that these compounds have limited potential for bioaccumulation/bioconcentration in biological organisms.

Fenamidone will pose a negligible risk to earthworms, honeybees, wild birds, wild mammals (based on acute exposure) and non-target terrestrial plants at the proposed application rate. However, the level of concern is exceeded for wild mammals (based on dietary and chronic exposure), beneficial insects, amphibians, and freshwater and saltwater invertebrates. Therefore, buffer zones to protect sensitive aquatic habitats are required during application. In addition, environmental hazard statements are required for protection of beneficial insects.

Value Considerations

What Is the Value of Fenamidone

A value assessment of Reason 500 SC Fungicide is presented in Regulatory Note REG2003-11. Since the publication of Regulatory Note REG2003-11, the directions for application of Reason 500 SC Fungicide alone at the rate of 400 mL/ha have been removed from the label. Application with aerial equipment has been added to the Reason 500 SC Fungicide label.

Reason 500 SC Fungicide is a foliar fungicide for control of early and late blight on potatoes, and is applied with ground or aerial equipment. It is a preventative, protecting fungicide that inhibits fungal spore germination, and acts as an antisporulant.

Reason 500 SC Fungicide must be tank-mixed with Dithane DG (mancozeb) or Bravo 500 (chlorothalonil) when applied. When Reason 500 SC Fungicide is applied as directed, it controls early and late blight disease at commercially acceptable levels.

The value of Reason 500 SC Fungicide is its strong activity against early and late blight on potatoes. In addition, it is an alternative to some of the older, less effective fungicide chemistries currently used as stand-alone products for control of late blight on potatoes. The rates at which the tank-mix partners are tank-mixed with Reason 500 SC Fungicide are at the low end of their registered rates. Therefore, less of these older chemistries are required to be applied.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Reason 500 SC Fungicide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

• Human Health

Because there is a concern with direct skin contact with fenamidone, people mixing or loading Reason 500 SC Fungicide must wear a long-sleeved shirt, pants, boots, protective eyewear and chemical-resistant gloves.

• Environment

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification.

Aerial application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply when wind speed is greater than 16 km/h at flying height at the site of application. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) coarse classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length MUST NOT exceed 65% of the wing or rotorspan.

Buffer Zones

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of Aquatic Habitat of Depths:	
		Less than 1 m	Greater than 1 m
Field sprayer*	Potatoes	1	0
Aerial - fixed and rotary wing		5	0

* For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%.

Consult the labels of the tank mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

Do not contaminate aquatic habitats when cleaning and rinsing spray equipment or containers.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

⁵ As per subsection 35(1) of the *Pest Control Products Act*.

References

2.0 CHEMISTRY

- PMRA 1108221 Stability of Reason 500 SC.
- PMRA 1108382 Analytical Profile of Five Production Batches Produced By SNPE, Toulouse, France, AE C649693, Fenamidone.

3.0 IMPACT ON HUMAN AND ANIMAL HEALTH

- PMRA 1108222 2005, Fenamidone and the Potential Formation of Aniline and Substituted Anilines in Crops, Bayer CropScience Inc., N/S, MRID: N/S, DACO: 7.4.3

4.0 IMPACT ON ENVIRONMENT

- PMRA 1108383 1997. RPA 408056 and RPA 717879 *n*-octanol/water partition coefficient. Study No. 97-136, Report No. R003445.
- PMRA 1108384 2005. Data on the Formation of Aniline and Substituted Anilines in Soil.
- PMRA 1108385 1998. RPA 407213, Toxicity to the Sediment Dwelling Chironomid Larvae (*Chironomus riparius*) - 28 days.

